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INTRAOPERATIVE CRYSTALLIZATION ON THE INTRAOCULAR LENS SURFACE

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ABSTRACT

Purpose: To report a physician survey, laboratory studies and clinical observations of intraoperative crystallization on the surface of the intraocular lens (IOL).

Method: We sent a survey to all ophthalmologists in the states of Wyoming, Idaho, Montana, Utah and Colorado asking whether crystallization on the IOL surface had occurred in any of their patients and what viscoelastics, IOLs, and other solutions were used. All returned surveys were tabulated and analyzed by standard statistical means. A sample of crystallization from an IOL on a glass slide submitted by a physician was analyzed to ascertain the relative elemental composition. During in vitro laboratory studies BSS Plus (Alcon Surgical Inc., Fort Worth, Texas) and BSS (Alcon Surgical Inc.) were measured and analyzed for precipitation. Healon GV (Pharmacia/Upjohn, Inc., Kalamazoo, Michigan) and $CaCl_2$ were combined in various solutions and examined for precipitate formation. Silicone IOLs and plate silicone were placed in different BSS and BSS Plus solutions with different viscoelastics and varying calcium concentrations. In seven patients, significant crystallization on an IOL surface was examined, photographed and followed for up to 3 years.

Results: Two hundred six surveyed ophthalmologists returned 181 (88%) surveys and reported 29,609 cataract surgeries with intraocular lens implantation with 22 (0.07%) eyes (22 patients) in which intraoperative crystallization was observed on the intraocular lens surface during 1993. The survey indicated there was a correlation with BSS Plus ($\chi^2 = 4.9$, P = 0.0268) and silicone intraocular lenses ($\chi^2 = 6.8$, P = 0.0093). The sample showed the cation to be calcium.

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Conclusion: Crystallization on the intraocular lens surface during cataract surgery is a rare occurrence that may be associated with calcium as the cation related to an osmotic gradient around the IOL with increased calcium concentration. If encountered surgically, the lens should be exchanged in the operating theater after irrigating the anterior chamber with BSS and completely filling the capsular bag with a low molecular weight viscoelastic.

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INTRODUCTION

Intraoperative crystallization on the surface of the intraocular lens (IOL) implant is a dramatic event. Diffuse crystals can suddenly appear on the intraocular lens (IOL) surface, immediately after insertion. This phenomenon has been previously reported,[1] but its incidence, etiology and prevention are unknown.

After four years of investigation, we report a physician survey, laboratory studies and clinical observations of intraoperative crystallization on the surface of the intraocular lens.

METHODS

A survey was sent to all ophthalmologists in the states of Wyoming, Idaho, Montana, Utah and Colorado. A clinical picture of a patient with crystallization on the IOL surface was included with the survey (Fig 1) and questions about whether this condition was seen, number of cataract cases performed, percentage of silicone or polymethylmethacrylate (PMMA) IOLs used, and percentage of viscoelastics and BSS (Alcon Surgical Inc., Fort Worth, Texas) or BSS Plus (Alcon Surgical Inc.) if used, for all of the cases performed in 1993. All returned surveys were tabulated and analyzed by standard statistical means.

One doctor in the survey submitted a sample of crystallization from an IOL on a glass slide. This specimen was cut in thirds by microdissection with one part analyzed by x-ray photoelectron spectroscopy for elemental identification. The remaining two parts were analyzed by scanning electron microscopy (SEM) and x-ray fluorescence to ascertain the relative elemental composition.

The following in vitro tests were performed and the results are listed:

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1) BSS Plus pH stability was measured in a beaker at room temperature for fifty hours. Measurements were made every 2 hours for four measurements and then occasionally throughout the 50-hour period. The pH stability over the entire 50 hours showed no significant drift and stayed at a value of 7.45, plus or minus 0.01, during the entire time for BSS Plus.
2) An analysis for precipitation of BSS Plus was performed with reconstituted BSS Plus at room temperature. A Brookhaven BI200 particle sizer with a 30 mW helium-neon laser light source was used to detect precipitates in the solution. The detection limit was 1.0 mg/ml for very small proteins. The solution was analyzed every 2 hours for 24 hours, then twice a day for 2 more days, for a total of 72 hours. Precipitation in BSS Plus was not noted for the entire period,
3) Five hundred microliter samples of Healon GV (Pharmacia/Upjohn, Inc., Kalamazoo, Michigan) were combined with a sample of 50 µL of 5.0 mM $CaCl_2$, 100 µL of 5.0 mM $CaCl_2$, 200 µL of 5.0 mM $CaCl_2$ and 500 µL of $CaCl_2$. These solutions were examined for precipitate formation. No precipitate was seen with the addition of 50-500 µl aliquots of 5.0 mM $CaCl_2$ to 0.5 ml of Healon GV.
4) On top of 500 µL of Healon GV, a 200 µL solution of blue Dextran (by Pharmacia, molecular weight of 2×10^6 gm/mol) was placed. The resulting diphasic solution was observed for any fluid shifts. The layering visibly demonstrated the rapid concentration of blue polymer in the ever-shrinking volume of superphase above the hyaluronic phase. There was obviously an osmotic gradient pulling water into the hyaluronate and concentrating the Dextran.

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5) Solutions of BSS and BSS Plus had $CaCl_2$ added in increasing concentrations until the calcium concentration was 20 mM. The solution was measured by UV absorbence at 254 nm to measure for precipitation. BSS+ was measured just after mixing, 5 and 15 minutes later. BSS and BSS Plus respond very differently to the addition of $CaCl_2$ as measured by UV absorbance at 254 nm. Through 20 mM $CaCl_2$ concentration BSS remained clear at all times, while BSS Plus showed increasing precipitation, especially after 3.0 mM $CaCl_2$ solution.
6) BSS and BSS Plus were mixed in a one-to-one ratio and measured by 254 nm UV absorbence for 24 hours for evidence of precipitation. A one-to-one mixture examined for 24 hours did not show any precipitation.
7) A STAAR plate silicone IOL (STAAR Surgical Company, Monrovia, CA) and an AMO SI-30 silicone IOL (Allergan Medical Optics, Irvine, CA) were each placed in a BSS Plus solution for 24 hours. The IOLs were then removed and examined by SEM for any crystallization on the surface of the lenses. There was no crystallization on the IOL surface.
8) A STAAR plate silicone IOL and an AMO SI-30 silicone IOL were each introduced into equal volumes of BSS Plus and Healon GV for 24 hours. These lenses were then removed and examined by SEM for any crystallization on the IOL surface. Silicone IOLs did not reveal any evidence of crystallization.
9) Two sets of each of the following were thoroughly mixed:
    1. 0.5 ml BSS Plus plus 0.2 ml Healon GV.
    2. 0.5 ml BSS Plus plus 0.2 ml Amvisc.
    3. 0.5 ml BSS Plus plus 0.2 ml Healon.

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Silicone ingots were washed with isopropanol, ethanol and distilled water, blot dried on filter paper, and placed in each of the six solutions. Calcium chloride was added to the solutions to vary the concentrations from 3.6 up to 14.4 mM of calcium by addition of $CaCl_2$. The silicone ingots were then examined visually for crystallization. A mixture of 0.5 ml of BSS Plus and 0.2 ml of Healon GV with a silicone ingot and additions of $CaCl_2$ did show a clear correlation with calcium ion content with those cells containing 7.2 mM calcium ion or above showing solution precipitates, while the surface of the silicone ingots remained clear to visual examination in all cases. In the presence of 3.6 mM calcium ion, the IOLs and solution remained clear for several hours; however, the solution turned cloudy overnight with no specific IOL deposit by visual examination accumulating on the silicone surface. For this experiment the Healon GV and BSS Plus were mixed to produce a homogeneous solution for placement of the silicone ingots so there was no superphase.

10) Fura-2 (CalBiochem, MW 751), a calcium binding fluorescence probe,[2] was mixed (1.0 mg) in 1.33 µL DMSO then diluted with distilled water to yield 10 µM solution. A standard curve was measured under dual excitation (340 and 380 nm) at fixed emission 510 nm using a Perkin-Elmer LB50 fluorometer. The solution showed a linear excitation curve up to 2.5 mM calcium with minimal changes in excitation after that up through a 15.0 mM calcium chloride solution.

11) Healon GV (0.85 ml), Healon (0.85 ml), Amvisc Plus (0.8 ml, Amvisc (0.8 ml) and Occucoat (1.0 ml) were added to triple washed glass cells. One hundred microliters (plus 1.0 µl of Fura-2 stock solution from experiment 10) of BSS Plus were added to the top of each viscoelastic and 100 µl of plain BSS plus 1.0 µl of stock Fura-2 were added to

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Healon GV only. Two microliter samples of the liquid phase on top were removed for calcium analysis by fluorescence as outlined in experiment 10 immediately after, 5 minutes and 15 minutes later. The BSS and BSS Plus solutions were rapidly absorbed into the viscoelastic so sampling the fluid superphase was difficult. By the time the pipette was introduced, there was a minimal liquid phase. Initial results did show the highest concentration of calcium in BSS Plus with Healon GV (3.25 mM) and the lowest with Amvisc Plus (1.0 mM); however, these differences were not statistically significant. Sampling at 5 and 15 minutes was of the viscoelastic with no fluid phase evident, and there were no differences noted with time.

12) Healon GV (0.85 ml) was placed in a triple washed glass cell. BSS Plus solution (0.5 ml) to which was added $CaCl_2$ to bring the calcium concentration to 7.2 mM was placed on top of the viscoelastic and an IOL added to the liquid phase. This was repeated for two silicone and two PMMA IOLs. After 15 minutes the IOLs were removed and examined by SEM with x-ray fluorescence to ascertain the relative elemental composition of any deposits. Light microscopic photos of all four IOLs revealed characteristic deposits not evident by unmagnified visual inspection. Deposits on the PMMA IOLs were typical feathery crystals similar in appearance to Fig 2. Deposits on the silicone IOLs were distinctive circular rings with some feathery irregularities also noted. These changes were consistent throughout the samples (Fig 3). Elemental analysis showed significant calcium only in the crystals themselves. Analysis of the PMMA lenses were difficult due to material melting so this observation was only definite with silicone lenses.

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Seven patients (seven eyes) with significant crystallization on an IOL surface using Healon GV with silicone IOLs in uncomplicated surgery were examined and photographed. These patients have previously been described and were followed for up to three years to obtain a natural history of this process.

RESULTS

Of the 206 surveys sent to ophthalmologists in the Rocky Mountain States, 181 surveys (88%) were completed (29,609 surgeries) and sent back to us for analysis. A total of 22 (0.07%) eyes (22 patients) of intraoperative crystallization were reported. Statistical analysis shows that there is a statistically significantly increased incidence of crystallization associated with the use of BSS Plus ($\chi^2 = 4.9$, $P = 0.0268$) and silicone IOLs ($\chi^2 = 6.8$, $P = 0.0093$). Although 50% of the cases were associated with Healon GV and Healon GV was used in only 8.1% of all cases, statistical analysis of such small samplings is not statistically valid. Word of our interest in this project prompted one physician outside the area to submit information for the same year. This physician had three cases of precipitation at the time of surgery.

SEM of the submitted clinical specimen showed a unique form of feathery crystal (Fig 2). Contiguous features were typically 10 µm or less in width with multiple such features arranged in a leaf-like fashion. X-ray fluorescence performed on both SEM specimens showed virtual coincidence of the analytical results in anatomic percent. The five most abundant elements quantifiable were sodium (19%), silicone (23%), chloride (23%), potassium (19%) and calcium (16%).

The specimen submitted for x-ray photoelectron spectroscopy using a Hewlett Packard 5950B spectrometer indicated presence of the following major components: sodium (12%), silicone (7.6%), carbon (42%), calcium (1%), nitrogen (0.4%), and oxygen (37%). The composition is quantified in an atomic percent of elements.

Because of the large number of in vitro tests performed, the results of each test were reported after the description of the test procedure in the Methods section.

The seven patients (seven eyes) with silicone lenses and significant crystalline deposits had varying degrees of symptoms as can be seen in Table 1 with clinical details previously described.[1] While two patients had macular degeneration, decreased vision to 20/40 from the deposits was felt to be documented in the absence of any other cause for decreased vision in at least two patients. While the majority cleared spontaneously, three years later some crystallization sequestered between the capsule and the lens has remained without decrease or change. In the one patient with 20/40 vision without additional pathology due to the lack of resolution of the crystals, a Nd:YAG capsulotomy was carried out with difficulty. The crystals seemed to concentrate the energy once the capsule was cut and resulted in a significant mark in the intraocular lens. Keeping away from the optical center, however, a posterior capsular opening was completed and there was resolution of the central crystals over a period of several months.

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DISCUSSION

The event of crystallization at the time of surgery is exceedingly uncommon; however, we have documented that it can be clinically significant and very persistent. It is important to remember that with an overall incidence of less than one in 1,000 cases, five ophthalmologists had two or more cases, usually closely grouped. One had three cases in the same day! On survey, the vast majority of ophthalmologists had never seen this phenomenon.

The clinical survey suggested an incidence of approximately one in 1,400 cases. The actual incidence is probably much lower. It is important to understand that our 12 cases (includes five additional cases on PMMA) and three cases from an outside ophthalmologist represent 15 of the total for just three surgeons and probably skews the incidence higher than it really is. We believe the true incidence is probably less than in one in 10,000 and explains why so many ophthalmologists have never encountered this phenomenon. The survey does help to correlate this finding with surgical variants, particularly BSS Plus and silicone intraocular lenses. While statistical analysis of any viscoelastic association is necessarily difficult to assess, it is known that 50% of cases occurred with Healon GV while Healon GV was used in only 8.1% of the cases.

Healon GV was identified early as a likely cause of crystallization since all of the original cases occurred when this product was used.[1] The overall incidence with Healon GV was 11 cases out of 278 (4%) cataract extractions. The theory, that crystallization was associated only when Healon GV was used, changed when an additional case occurred with the use of Amvisc Plus (Chiron Vision Corporation, Claremont, California). It was further discovered that crystallization could occur with Occucoat (Lederle Laboratory Division, American Cyanamide

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Company, Pearl River, NY) and other viscoelastics as well. Healon GV remained a concern but was not considered to be the sole cause.

Correlation with silicone appeared to be strong with no cases of significance having been noted on PMMA. Five instances of precipitation on PMMA were so minimal that it was only visible to two experienced viewers who had seen previous silicone IOL crystallization. Probably this finding would be missed by most observers. Silicone appears to be a substrate that is more sensitive to extensive crystallization.

BSS Plus is related to this phenomenon by statistical analysis. Although the calcium concentration of BSS Plus reconstituted is significantly lower than BSS (1.0 vs. 3.25 mM) the citrate in BSS allows this solution to accommodate calcium ion in excess of 20 mM without showing signs of turbidity. BSS Plus, on the other hand, shows an increase in turbidity with concentrations above 3.5 mM which drastically increases when above 7.0 mM. In fact, it is hard to understand how this phenomenon could occur with BSS plain due to the citrate component.

The specimen was extremely serendipitous, but we recognize, however, that this is not our typical case. The crystallization that we have seen does not come off of the lens surface either by irrigation or by instrumentation. It is gritty and exceedingly adherent to the intraocular lens surface. The actual crystalline component of this star-fish-shaped specimen is similar in appearance although it appears to have occurred in a different matrix (probably fibrin). The specimen suggests that calcium is the cation of concern. This is corroborated by our in vitro recreation of the clinical situation in experiment 12. The similarities of these crystals and the crystals in this experiment also suggest that this case is probably related.

It should be pointed out that the discrepancy in relative atomic percentages is most likely due to the differences in the spot size analyzed in the two approaches. X-ray photoelectron

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spectroscopy is based on a collected signal from a 5.0 mm^2 surface area while the scanning electron microscopy x-ray fluorescence analysis was collected from an area of approximately 250 μm^2. In addition to spot size, the two analyses probe different depths with x-ray photoelectron spectroscopy sampling the uppermost 50 Å while x-ray fluorescence samples significantly deeper layers. Thus, while the sensitivity of the SEM techniques is lower, it has the advantage of reporting the composition of specific features of interest which in this case are the crystals themselves. Both techniques report the presence of silicone as is expected from the glass mount. We don't feel that silicone is any part of the actual crystallization. The high content of sodium is also partially contributed by the glass substrate, but must in part stem from the deposit. The small amount of nitrogen with a carbon-to-nitrogen ratio of 100 to 1 is much lower than what is typically observed on protein containing surfaces and, therefore, allows us to rule out the possibility that the precipitate is primarily protein. Although we feel the elemental analysis at least shows us that the cation of concern is calcium, it really gives us no clear clue as to the anion except to be able to exclude phosphorus-containing compounds.

In vitro analysis was a series of steps that gave a fairly clear picture of what occurred. It is reassuring to know that either BSS Plus and/or BSS Plus with Healon GV alone would not result in precipitation with or without a silicone IOL. The addition of blue Dextran, however, did reveal the possibility of an osmotic gradient in a diphasic solution drawing water into the viscoelastic and concentrating the solutes in the liquid nonhyaluronic phase. We also were able to show that precipitation on both PMMA and silicone surfaces consistently occurred at a 7.2-mM calcium concentration. The deposits were different when looking at PMMA and silicone which may mirror the clinical clue that silicone is necessary for deposits of clinical significance.

Our theory is that viscoelastics produce an osmotic gradient with Healon GV creating the greatest colloidal pressure. With an anterior chamber filled with a viscoelastic, the IOL makes its way into the capsule and into a liquid phase with solutes rapidly concentrating. Due to the osmotic gradient, abnormal concentrations of calcium can rarely occur under these circumstances resulting in precipitation on the IOL surface. Subclinical deposits may be very common. Due to the citrate present in BSS, such precipitation could only occur at very high calcium concentrations or possibly where there is minimal to no BSS and only normal calcium containing aqueous sequestered in the capsular remnant. What is clear to us is BSS would be very resistant to this phenomenon. The third part of the equation is that the silicone substrate lends itself to the diffuse and clinically significant crystallization as has been seen in patients. The work by Shumakov et al[5] suggests in vitro that silicone was more sensitive to calcification than polyurethane and polyethylene.[5] While not directly related, we feel this work on biomaterial calcification is supportive of our thesis.

This theory appears to explain our observed correlations from the survey and just how the phenomenon may occur. It doesn't explain the one case reported to us from our survey with unusual crystallization immediately after intracameral acetylcholine solution irrigation. We did not include this case in our results due to the diffuse crystallization which resolved in 10 days. We have not heard of nor can find a similar case in the literature and report this here for completeness sake.

Calcification of the superficial corneal stroma associated with an older preparation of Viscoat (Alcon Surgical Inc., Fort Worth, Texas) and dystrophic calcification of silicone scleral buckling implant materials have been well documented in the literature,[3,4,6] but what we have observed with immediate calcification in the operating room is a different problem.

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Unusual crystalline material discovered within a PMMA posterior chamber lens with polypropylene haptics seven to eight years after implantation,[7] is unrelated to the phenomenon we describe. It is also not related to PMMA intracorneal implants which have shown a crystalline aggregate in the deep corneal stroma behind the implant.[8,9]

In summary, we have described crystallization on IOLs with calcium as the cation that we feel is related to an osmotic gradient created by the viscoelastic resulting in increased calcium concentration (usually with BSS Plus) resulting in precipitation and crystallization on the surface of silicone lenses in all clinically significant cases.

RECOMMENDATIONS FOR MANAGEMENT

Intraoperative crystallization on an IOL is rare: however, one surgeon encountered three cases in one day. Generally, crystals on the intraocular lens cannot be removed. We would remove such an IOL immediately, fill the posterior chamber with plain BSS followed by a retentive viscoelastic, and implant a new IOL.

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FIGURES

Figure 1: A clinical slit lamp photo of a 82 year old male, 8 months after surgery with moderate and typical crystallization (arrow) on a silicone IOL.

Figure 2: **Scanning electron microscopy** (SEM) of crystalline deposits peeled from an IOL at surgery. Top photo at 490X shows a feathery pattern to the crystals. Bottom photo shows the same crystals at 6800X.

Figure 3: Scanning electron microscopy at 100X of deposits created in vitro on a PMMA IOL (top) and a silicone IOL (bottom). Characteristic deposits were consistent and different for both materials.

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Table 1: Summary of patient severity, visual acuity and most recent outcome of crystalline precipitates on silicone IOLs.

Patient #	Age	Sex	Eye	Description of Severity*	Impact on Visual Acuity	Length of Follow-up	Clinical course of crystallization
1	76	F	OD	+1	20/20 None 20/20 last exam	6/8/93-5/8/96 (35 months)	Cleared with a few sequestered crystals. Not clinically significant
2	83	F	OS	+2	20/40 Best at first. Improved to 20/20	7/6/93 – 10/18/95 (27 months)	Cleared with a few sequestered crystals.
3	50	M	OS	+1	None (20/20 at last exam)	8/10/93 – 8/1/96 (36 months)	Deposits sequestered by capsule still present
4	82	F	OS	+3	20/60 before laser capsulotomy 20/30 after	8/18/93 – 2/8/94 (6 months)	Central clearing after a difficult laser capsulotomy. Visual acuity when last seen was 20/30. No other pathology that could decrease vision was noted.
5	81	M	OS	+3	20/100 (Macular Degeneration)	8/18/93 – 11/8/94 (15 months)	CF advanced macular degeneration at last exam. No clearing where sequestered by capsule. Now deceased.

6	84	F	OS	+1	20/25 at 3-month postop. 20/40 last exam.	9/8/93 – 8/6/96 (35 months)	Not ever clinically significant and had cleared with early macular degeneration noted at last exam.
7	87	F	OS	+2	Blurred vision, 2+ central corneal edema, 20/200	10/13/93-5/14/96, 32 months.	Edema/blurred vision first postoperative day. At 3-week visit, visual acuity was 20/30, later improving to 20/20. 1+ crystals last seen 1/10/95 (15 months postop).

* Severity description was determined by examination of the photographs taken for each patient on the first postoperative day. Photographs that showed the greatest density of crystallization were assigned a severity of +3, and photographs that showed the least density were assigned a severity of trace. A level +3 severity would be dense/white/crystals in high concentration with central location felt to affect visual acuity. Severity of 2+ is moderately dense possibly affecting visual acuity still widely spread along surface of lens. A +1 severity is scattered crystals/non-dense, not affecting visual acuity, randomly scattered across the lens surface and not necessarily centrally located.

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